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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,386	04/12/2004	Bryan W. Vidler	STD 1222 PA/41213.596	2855
23368 7590 10/15/2007 DINSMORE & SHOHL LLP ONE DAYTON CENTRE, ONE SOUTH MAIN STREET SUITE 1300 DAYTON, OH 45402-2023			EXAMINER WILLIAMS, JAMILA O	
			ART UNIT 3722	PAPER NUMBER
			MAIL DATE 10/15/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/822,386

Applicant(s)

VIDLER ET AL.

Examiner

Jamila Williams

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 3,5,7-12 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,6,13,15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 4, 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over 7,048,308 to Blank.

Blank discloses a data carrier comprising a release liner (18), a health information label (14) having an upper and lower surface (figure 1 shows upper surface and figure 3 shows the lower surface) including a first area on the upper surface for indicia (area on the upper surface that includes "PHARMACY") and a second area on the upper surface for indicia (area on upper surface that includes "QUANTITY").

Blank discloses a pressure sensitive adhesive coating on the lower surface (adhesive 20) of the label securing the label to the release liner (figures 5 and 6) and a masking label integral with the health information label (32, see also figure 5 and column 4 lines 38-54 in that the label 32 can be removed and adhered to another object it is a masking label). A die cut in the release liner (18) defining a removable liner piece beneath the masking label (40), the removable liner piece being removable from the release liner with the health information label and remaining thereon when the health

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information label is applied to a surface (figure 3), the removable liner piece permitting the removal of the masking label from the label so that the masking label can be applied over one or both of the first and second areas to obscure the association of identity of the patient and the health related information when the data carrier is discarded (see figure 5 and column 4 lines 38-54, in that the masking label 40 can be removed from the label 14 and adhered to another object, it is inherently capable of being applied to the first or second areas of label 14 via the adhesive 20).

Blank disclose the claimed invention except for the specific arrangement and/or content of indicia set forth in the claim(s). It has been held that when the claimed printed matter is not functionally related to the substrate it will not distinguish the invention from the prior art in terms of patentability. *In re Gulack*, 217 USPQ 401, (CAFC 1983). The fact that the content of the printed matter placed on the substrate may render the device more convenient by providing an individual with a specific type of information does not alter the functional relationship. Mere support by the substrate for the printed matter is not the kind of functional relationship necessary for patentability.

The examiner asserts that the data carrier comprising a release liner, label, adhesive, masking label, die cut, removable liner piece of Blank is the same structure claimed by applicant and the sole difference is in the content of the printed material. Thus, there is no novel and unobvious functional relationship between the printed matter (e.g. indicia) and the substrate (e.g. label), which is required for patentability.

Accordingly, there being no functional relationship of the printed material to the substrate, as noted above, there is no reason to give patentable weight to the content of the printed matter which, by itself, is non-statutory subject matter.

Regarding the limitations of the preamble, the data carrier of Blank is inherently capable of providing health related information regarding a patient and for facilitating compliance with HIPAA by obscuring the association between the identity of the patient and health related information when the data carrier is to be discarded, in that the structure of the data carrier is met by Blank and the arrangement and/or context of the indicia is addressed by In re Gullack above.

Regarding claim 2, Blank discloses the first and second areas of are on a first portion of the label (the peripheral edge portions of the label, which is being defined as the portions where "PHARMACY" and "QUANTITY" are located in Blank) and the masking label is on a second portion of the label (the interior portion of the label, where 32 is located of Blank), the first and second portions being separated by a line of die cut perforations (38 of Blank).

Regarding claim 4, Blank discloses the pressure sensitive adhesive coating on the lower surface of the label comprises a permanent adhesive (Blank discloses that the label permanently bonds on the container in column 5 lines 33-35, therefore the adhesive 20 is inherently a permanent adhesive).

Regarding claim 13, Blank discloses a release liner (18), a first label (14) having an upper and lower surface, the label including a first and second area for indicia (see areas of "PHARMACY" and "QUANTITY"), pressure sensitive adhesive coating on the

lower surface of the first label (adhesive 20), second label integral with the data carrier and defined by a die cut in the first label (second label 32), the second label configured such that upon removing the first label from the release liner, the second label remains with the first label when the first label is adhesively applied to a surface (figure 3) and when the second label is subsequently separated from the first label the second label is adapted to disassociate the identity of the patient from the health related information (in that the structure of the label is met by Blank, it is inherently capable of this function). Regarding the specific indicia, see the In re Gullack rejection applied to claim 1 above.

Regarding claim 15, Blank discloses the second label (32) is defined by a die cut (38) in the first label (14).

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blank in view of 4,549,750 to Stone et al (hereinafter Stone). Blank discloses all elements of the claims but for the masking label being smaller than the removable liner piece beneath the masking label and the liner piece extending beyond the edge of the label such that the removable liner piece may be used to remove the masking label.

Stone teaches having a label (12 of Stone) with a removable liner piece (portion of liner 15 defined between score lines 16 in figure 2 of Stone), the removable liner piece extending beyond the edge of the label (see figure 1 element 18 and column 4 lines 3-5 of Stone). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the extending liner teaching of Stone with the removable liner and label of Blank for the purpose of allowing for easier removable of the label.

***Response to Arguments***

Applicant's arguments filed 7/12/2007 have been fully considered but they are not persuasive.

The 112 rejection of the previous rejection has been withdrawn because of applicant's amendment to the claims.

Regarding applicant's assertion that the examiner ignored the claimed limitations towards the printed matter, the examiner respectfully disagrees. The examiner fully considered applicant's claimed printed matter but concluded that the printed matter would not be deemed as having patentable weight. The examiner maintains that there is no functional relationship between the printed matter and the substrate.

Applicant's arguments regarding *In re Ngai* are also noted. However the holding in *Ngai* does not appear to support applicant's argument in this case. *Ngai* would appear to support the holding that the claimed invention was in fact anticipated by *Blank*.

Additionally, the argument towards the sizing of the label is not supported by the holding in either *Gulack* or *Ngai*. On the other hand, based on the skill level of one having ordinary skill in the relevant art, the examiner believes that those expedients such as sizing of a label would have been obvious if not clearly shown by the prior art.

Applicant's argument regarding element 40 of *Blank* is also noted. However as shown in figure 3, there is an adhesive material that is inherently capable of being applied over the areas as claimed.

For the reasons as set forth above, the rejections are maintained.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jamila Williams whose telephone number is 571-272-4431. The examiner can normally be reached on Monday-Thursday 6:00am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Monica Carter can be reached on 571-272-4475. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



JW 10-1-2007

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SUPERVISORY PATENT EXAMINER